REMARKS/ARGUMENTS

I. Status of the Claims

Claims 1-115 were originally filed. Claims 29-104 were subsequently canceled. Upon entry of the present amendment, claim 28 is further canceled, whereas claims 1, 4, 7, 9, 11, 12, 14, 15, 18, 22, 27, 105, 107, and 109-114 are amended as follows:

The word "pharmaceutical" is deleted from the phrase "pharmaceutical composition." The phrase "a *Mycobacterium* species of the tuberculosis complex" is replaced with "*Mycobacterium tuberculosis*." The phrase "full length" or "(FL)" is deleted from before or after "HTCC#1" and "TbH9." The phrase "HTCC#1 antigen" or "HTCC#1" is further replaced with SEQ ID NO:14 when specific amino acid residues are referred to. In claim 18, the word "immungenic" is a typographic error and has been replaced with "immunogenic." The present amendment does not introduce any new matter.

II. Objections

The specification was objected to for lack of current status of related U.S. patent applications. The present amendment has provided the required update.

Claim 18 was objected to for the misspelling of the word "immunogenic." This typographic error has been corrected.

III. Claim Rejections

A. 35 U.S.C. §112 First Paragraph

Claims 1-28

The Examiner rejected claims 1-28 under 35 U.S.C. §112 first paragraph, alleging inadequate enablement. Specifically, the Examiner asserted that since the claims are drawn to "pharmaceutical" compositions, yet the specification does not teach how to use the compositions to prevent, diagnose, or treat diseases in a patient, the use of the claimed invention is thus not enabled. Applicants respectfully traverse the rejection in light of the present amendment.

As amended, the word "pharmaceutical" has been deleted from all relevant claims. The pending claims are directed to compositions comprising fusion polypeptides, each of which comprises at least two antigens from *Mycobacterium tuberculosis*. The specification teaches various uses of such compositions. For example, on page 3 lines, 11-16, the specification teaches the use of such fusion polypeptides for *in vitro* and *in vivo* assays to diagnose and monitor *Mycobacterium tuberculosis* infection. Also on page 3, lines 20-28, the specification teaches the use of the fusion polypeptides as immunogens to generate or elicit protective immunity against *Mycobacterium tuberculosis* in a patient. Thus, the claimed compositions have multiple uses and at least some of the uses (*e.g.*, *in vitro* diagnostic use of the fusion polypeptides to detect antibodies against *Mycobacterium tuberculosis*) are immediately apparent to those skilled in the art. These uses are also fully enabled immediately upon the disclosure of the coding sequences of the *Mycobacterium tuberculosis* antigens of the fusion polypeptides, given the level of technical sophistication in the relevant art.

MPEP § 2164.01(c) describes the enablement standard for compound and composition claims as follows:

> [W]hen a compound or composition claim is not limited by a recited use, any enabled use that would reasonable correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use. . . . In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention.

Under this standard, the compositions as recited in the currently pending claims are sufficiently enabled. Applicants thus respectfully request the withdrawal of the enablement rejection.

Claims 1-28 and 105-115

The Examiner also rejected claims 1-28 and 105-115 under 35 U.S.C. §112 first paragraph, alleging inadequate enablement. Specifically, the Examiner stated that although the claims are enabled with regard to antigens from *Mycobacterium tuberculosis*, they are not as far as antigens from other species of the tuberculosis complex.

The amended claims now recite "*Mycobacterium tuberculosis*" instead of "a *Mycobacterium* species of the tuberculosis complex." As such, Applicants submit that the enablement rejection on this ground is overcome.

B. 35 U.S.C. §112 Second Paragraph

The Examiner further rejected claims 7-28 and 109-115 under 35 U.S.C. §112 second paragraph for alleged indefiniteness. Specifically, the Examiner pointed to the phrases "an HTCC#1 antigen" and "a full length HTCC#1 antigen" and questioned their difference. Moreover, the Examiner suggested the use of "SEQ ID NO:14" instead of "HTCC#1" where specific amino acid residues are referred to.

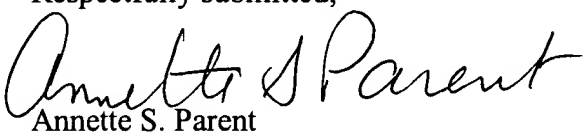
In response, the phrase "full length" is deleted from pending claims after the present amendment, and "SEQ ID NO:14" is recited in place of "HTCC#1" where reference to amino acid residues is made. Applicants therefore request the withdrawal of the indefiniteness rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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